Burundi National Laboratory Assessment, 2013

Report on Burundi National Laboratory Assessment, Conducted by SCMS and CDC Cameroon withUS Government-Funded Technical Assistance

Conducted: August, 2013

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Acknowledgements

The authors wish to thank all the partners, both governmental and non-governmental, whose staff helped to ensure the success of the comprehensive data collection exercise that informed the outputs associated with this laboratory assessment. A special thank you goes to NephtaliNkurunziza, the SCMS Laboratory Advisor, for his leadership in coordinating in-country efforts in close collaboration with local government counterparts and the USG mission.

About SCMS

The Supply Chain Management System was established to enable the unprecedented scale-up of HIV/AIDS prevention, care and treatment programs in the developing world. SCMS procures and distributes essential medicines and health supplies, works to strengthen existing supply chains in the field, and facilitates collaboration and the exchange of information among key donors and other service providers. SCMS is an international team of 16 organizations funded by the US President's Emergency Plan for AIDS Relief (PEPFAR). The project is managed by the US Agency for International Development.

This document was made possible through support provided by the US Agency for International Development, under the terms of contract number GPO-I-00-05-00032-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the US Agency for International Development (USAID) or the US government.

Recommended Citation

Williams, J. and Shang, J, August 2013. *Burundi National Laboratory Assessment, 2013.*Submitted to PEPFAR Burundi by the Supply Chain Management System (SCMS).

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Acronyms

ADP – Associate Deputy Principal

ART – Anti Retroviral Therapy

ASLM – African Society of Laboratory Medicine

ATLAS - Assessment Tool for Laboratory Services

BBS - Burundi Bureau of Standards

CAMEBU - Central d'Achat des Medicaments au Burundi

CCM – Country Coordinating Mechanism

CDC – Centers for Disease Control and Prevention

CD4 - cells - cluster of differentiation 4 cells

CHUK – Le Centre Hospitalo-Universitaire de Kamenge

COP – Country Operational Plan

CPSD - Cadre de concertation des Partenaires pour la Santé et le Développement

DHS - Demographic and Health Survey

DoD – Department of Defense

DP – Deputy Principals

DPML - Departement de la pharmacie, médicaments et laboratoires (Department of Pharmacy, Medicines and Laboratories)

EAPHLN - East Africa Public Health Laboratory Network

EID – Early Infant Diagnosis

EU – European Union

FBO - Faith Based Organization

FEFO - First Expired, First Out

GF – Global Fund

GOB – Government of Burundi

GPS - Global Positioning System

HC - Health Centers

HIV/AIDS – Human Immunodeficiency Virus/Acquired immunodeficiency syndrome

HR – Human Resources

HTC – HIV Testing and Counselling

INSP - National Institute of Public Health

LMIS - Logistics Information Management System

MOH – Ministry of Health

MSH – Management Sciences for Health

NAP - National Aids Program

NSP - National HIV Strategic Plans

OGAC – Office of the U.S. Global AIDS Coordinator

PBF - Performance Based Financing

PCR - Polymerase Chain Reaction

PEPFAR – President's Emergency Plan for AIDS Relief

PNLS – Programme National de Lutte contre le SIDA

PMTCT – Prevention of Mother to Child Transmission

PMI – President's Malaria Initiative

PPE – Personnel Protective Equipment

ROI – Return on Investment

SCMS – Supply Chain Management System

SOP - Standard Operating Procedure

STI – Sexually Transmitted Infection

STTA – Short Term Technical Assistance

TA – Technical Assistance

TB – Tuberculosis (Tubercle Bacillus)

TWG – Technical Working Group

UNICEF – United Nations Children's Fund

USAID – United States Agency for International Development

WB – World Bank

WHO – World Health Organization

ZN- Ziehl-Neelsen

Executive Summary

During the PEPFAR Deputy Principal (DP) and Associate Deputy Principals' (ADP) field visit to Burundi in September 2012, weaknesses were noted in the delivery of laboratory services at the central level and peripheral level, in both PEPFAR and non-PEPFAR supported heath facilities. In their report, the DP/ADPs recommended that technical assistance should be provided to assist the Government of Burundi in identifying gaps and making strategic recommendations that will guide the country on how to improve the availability and quality oflaboratory services.

In response, the PEPFAR Burundi team requested SCMS to lead a detailed laboratory assessment, in collaboration with the Government of Burundi, in-country partners and twolaboratory experts from SCMS HQ and CDC Cameroon.

The purpose of the the short term technical assistance (STTA) was to assess the quality and availability of national laboratory services in anticipation of the scale-up of prevention of mother-to-child transmission (PMTCT) services, which will include ART at PEPFAR-supported, GOB - supported and private facilities delivering HIV/AIDS clinical services. The technical assistance team assessed the overall lab situation in Burundi (both PEPFAR and non-PEPFAR sites), with a primary focus on the following objectives:

1. Reviewing availability and implementation of national laboratory policies;
2. Assessing the quality of services;
3. Assessing the impact of existing supply chain processes;
4. Assessing equipment maintenance; and
5. Determining recommendations for the establishment of efficient lab networks throughout the country

Over the course of four days of team site visits and data collection activities, a total of 137 sites were visited, with 15% of sites visited being supported by PEPFAR, and the remaining constituting nationally supported sites. Sites were split between hospitals, district and general health centers, and 1 national public health laboratory (National Institute of Public Health).

The most significant challenge identified as an outcome of this assessment is that Burundilacks an endorsed and implemented national laboratory policy, strategic plan, and nationally endorsed guidelines in respect to human resource planning, overall administration, coordination, procurement, minimum health packages/services, and standardized laboratory practices and techniques.A preliminary framework for developing a national policy was establishedin 2005, but a finalized national laboratory policy document has yet to be completed and endorsed for national implementation. In response, laboratories have developed and implemented site specific policies to assist in regulating laboratory service delivery and general practice. Although commendable at

the site level, this has led to considerable variation in laboratory service delivery practices, quality of services, and general safety practices. Site level data has been analyzed to demonstrate the overall impact of this centraladministrative issue to further demonstrate service delivery point linkages and overall impact where possible throughout this report.

To address the existing challenges detailed within this report, a national laboratory TWG should be established as soon as possible to develop an immediate, short, and a long term implementation strategy (way-forward plan). This group should serve as the responsible group for developing national laboratory policies and a national strategic plan on behalf of the MOH. Constituents should be varied, and include clinicians, laboratorians, donors, implementing partners, and key leaders that can advocate for laboratory development and ensure the coordination of stakeholders and donors. The overall aim of this group is to serve the interests of the Government of Burundi by providing strategic guidance on national laboratory systems strengthening and their overall stake in responding to the health demands of the populations.

Background

Burundi faces a low-prevalence, generalized HIV/AIDS epidemic that remains a public health threat. The Demographic and Health Survey (DHS) conducted in 2010 showed that the general HIV prevalence is at 1.4%, with infection rates among women higher than men (1.7% versus 1%). The PLACE Study completed in 2013 estimates the HIV prevalence among female sex workers nationally is 22.5 %. HIV prevalence rates among other key populations are lower: among men who have sex with men 6%; prisoners; 3%, and seasonal workers 1.4%. The PMTCT coverage in Burundi remains low and is 38% in 2011. Available data suggest that the main drivers of the epidemic include heterosexual transmission through multiple concurrent partnerships, including transactional, intergenerational, and commercial sex; low condom use; and weak knowledge about HIV.

In an effort to improve the national response to HIV/AIDS, Burundi has joined several international initiatives, including the Commitment Declaration on HIV/AIDS, prevention acceleration, the 3X5 initiative, and universal access to prevention, treatment, care and support. The New Partnership for Africa's Development, to which Burundi adheres, offers other opportunities for the accomplishment of the African Union Objectives related to HIV/AIDS and of the Millennium Development Goals.

Since 2002, Burundi has drafted three National HIV Strategic Plans (NSPs) with the objective of defining clear priorities to guide the interventions of various donors. The most recent NSP 2012-2016 was prepared with technical assistance from USAID/Burundi PEPFAR and sets realistic objectives for prevention, treatment, care and support in light of the current financial environment. The implementation of the 2007-2011 NSP led to substantial achievements in the area of HIV testing sites, ART sites, and care and support for people living with HIV/AIDS.

During the PEPFAR Deputy Principal and Associate Deputy Principals' field visit to Burundi in September 2012, weaknesses were noted in the delivery of laboratory services at central level and peripheral level, in both PEPFAR and non-PEPFAR supported heath facilities. In their report, the DP/ADPs recommended that technical assistance should be provided to assist the Government of Burundi to improve the availability and quality of laboratory services.

In response the PEPFAR Burundi team requested SCMS to lead a detailed laboratory assessment, in collaboration with in-country partners (Ministry of Health, INSP, CHUK, PNLS/IST) and twolaboratory experts from SCMS HQ (Jason Williams) and CDC Cameroon (Dr. Judith D. Shang).

The purpose of the short term technical assistance (STTA) was to assess the quality and availability of national laboratory services in anticipation of the scale-up of prevention of mother-to-child transmission (PMTCT) services, which will include ART at PEPFAR-supported, GOB -supported and private facilities delivering HIV/AIDS clinical services. The technical assistance team assessed the overall lab situation in Burundi (both PEPFAR and non-PEPFAR sites), with a primary focus on the following objectives:

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As mentioned earlier, Burundi has drafted three National HIV Strategic Plans (NSPs) with the most recent NSP 2012-2016 being prepared with technical assistance from USAID/Burundi. The 2007-2011 NSP has led to substantial achievements in the area of HIV testing sites, ART sites, and care and support for people living with HIV/AIDS, but an overall laboratory network development and response strategy still remains missing.

The laboratory organization structure within Burundi reflects the overall structure of the health system which is defined on three levels: central, intermediate, and peripheral. The laboratory sector is vast and is comprised of:

- 66 laboratories within hospitals in public, Faith Based Organization (FBO) hospitals and private sector,
- 801 laboratories in public, FBO and private health centers and dispensaries
- 21 laboratories supported by local associations and NGO facilities.

The district hospital laboratories serve as referral facilities for all health center laboratories within the district. The health center laboratories perform a limited number of tests, including HIV rapid testing. In addition to the tests performed at the health center level, district hospitals can perform and provide more complex testing services such as those associated with hematology, biochemistry, serology, and flow cytometry for CD4 cell counts.

The central level is comprised of twonational laboratories, which include the National Institute of Public Health (INSP) and the CHUK National laboratory. They provide the most sophisticated laboratory tests and serve as reference laboratories for the whole country.

Process, Methodologies and Tools

Following arrival in country, the STTA providers met with the MSH Country Director, SCMS Field Program Officer, and the SCMS Laboratory Logistics Advisor. The meeting was held on Tuesday 13th, 2013 at the MSH Burundi main office. The intent of the meeting was to debrief on the current progress related to site visit team training, site visit schedules, the data analysis plan, identify any existing gaps or challenges associated with the TA, clarify any core questions related to the scope of work, discuss the overall agenda for the upcoming two weeks, and the general approach for completing the required scope of work.

A formal out-brief was held with USAID and the U.S. Ambassador on August 23rd. The TA providers and the MSH Country Director attended the meeting. The debrief provided an opportunity to discuss the overall assessment approach, initial findings based on data collected during site visits, and general perceptions associated with the STTA provider visits. Key points included:

- Process and preliminary findings from the nationwide laboratory assessment;
- Recommendations related to the next steps for the strengthening of the national laboratory system including possible implications for the upcoming COP 2014 and Global Funding proposal development;
- Possible technical assistance available and the required synergy between the GOB, the Global Fund, and PEPFAR.

Process

The STTA providers arrived and remained in-country for twoweeks, working closely with the SCMS team in Burundi, and the Departement de la pharmacie, medicament et laboratoire (Department of Pharmacy, medecines and laboratories or DPML), as well as other Ministry of Public Health and the Fight against AIDS (MSPLS)departments (Demand & Supply of Health Services,National Institute ofPublicHealth (INSP, National AIDS and Sexually Transmitted InfectionsProgram (NAP, TB program, and the national malaria program. A summary of activities are detailed below:

- From August 12 to 20, 2013: Data collection process including training on the Assessment tool for Laboratory services(ATLAS developed by USAID/DELIVER Project and data collection in 137 laboratories both sampled in public and private sectors in all the 17 provinces;
- From August 21 to 22, 2013: Data analysis and development of preliminary findings and report;

- August 23rd: SCMS Burundi office and TA providers debriefed the Ambassador and the PEPFAR team on findings and recommendations.

Expected results:

- All MOH stakeholders were to be provided with: a comprehensive view of all aspects of the laboratory services and supply chain; a snapshot of testing capabilities and commodity availability at laboratories throughout the system; and with country-oriented recommendations and inputs for developing a national strategy for improving laboratory services in Burundi.
- The capacity of the assessment team in-country would haveenhanced skills in conducting a national assessment using the ATLAS tool.
- A final report would be developed with key findings and recommendations to improve the laboratory services in Burundi, specifically to successfully improve the performance of HIV testing sites, ART sites, and the care and support for people living with HIV/AIDS.

In-country stakeholders involved in this assessment:

- Departments within the Ministry of Health including vertical programs: Direction Générale des Services de Santé, DPML, Direction du Budget et Approvisionnement, Demande et Offre Des Soins (DODS), IRA,PNLS/IST, PNILT, INSP, CAMEBU, SEP/CNLS, CNTS
- Ministry of Finance,
- In-country stakeholders : CED CARITAS, AMAGARA MEZA, East Africa Public Health Laboratory Network (EAPHLN), Belgian Cooperation, USAID/PEPFAR, MSH/SCMS, World Health Organization, UNICEF, ONUSIDA, FHI360, Project ESTHER.

Prior to arriving in-country, the STTA providers worked collaboratively with the SCMS country team, various departments within the Ministry of Health, and the USAID mission to develop the overall assessment visit approach and tool to be used for the assessment. The sampling methodology and national reach was also established (Table 1). The final data collection tool is provided as an annex to this report.

Table 1: Sampling distribution for site assessment visits.

Province	HC	Districts	Regional	NRL	Visits
Bubanza	3	1	2		6
Bujumbura rural	3	1	3		7
Bururi	3	1	4		8
Cankuzo	3	1	2		6
Cibitoke	3	1	2		6
Gitega	3	1	4		8
Karusi	3	1	1		5
Kayanza	3	1	2		6
Kirundo	3	1	2		6
Makamba	3	1	2		6
Muramvya	3	1	2		6
Muyinga	3	1	3		7
Mwaro	3	1	1		5
Ngozi	3	1	4		8
Rutana	3	1	2		6
Ruyigi	3	1	2		6
Mairie de Bujumbura	3	1	30	1	35
TOTAL	**51**	**17**	**68**		**137**

Over the course of four days of site visits and data collection activities, a total of 137 sites were visited as originally proposed, with 15% of sites visited being supported by PEPFAR (all PEPFAR sites were visited as part of this assessment), and the remaining constituting nationally supported sites. Sites were split between hospitals, district and general health centers, and 1 national laboratory. Site composition wasequally spilt between hospitals and health centers, 68 each. A summary of the final site visit distribution is provided in Table 2.

Table 2: Final distribution of sites visited for PEPFAR vs. Non-PEPFAR sites.

	PEPFAR	**Non PEPFAR**	**Total**
Hospitals	9	59	68
Health Centers	12	39	51
Health Districts	4	13	17
National Reference Lab (INSP)		1	1
Total	21	112	137

Methodologies and tools

The Assessment Tool for Laboratory Services and Supply Chains (ATLAS) was selected for use in this assessment and then customized to ensure situational context by the in-country SCMS team. The ATLAS is a comprehensive data gathering tool developed by the USAID | DELIVER PROJECT for assessing national laboratory systems and a diagnostic and monitoring tool which can be used as a baseline survey, measuring changes in the laboratory system in response to specific interventions, in addition to serving as an integral component in work planning development and establishing priority response strategies. The ATLAS is both a quantitative and qualitative tool. The ATLAS provides a comprehensive overview of how a laboratory's supply chain and the structures that support its overall operation function.

The tool contains two core components, a Central/Intermediate Administrative Level, and the Facility Level Questionnaire.

The Central/Intermediate Administrative Level Questionnaire includes:

- Organizational Structure
- Policy
- Quantification
- Procurement
- Financing
- Storage and Distribution
- Inventory Control System
- Laboratory Services Management Information System
- Supervision
- General Questions

The Facility Level Questionnaire includes questions associated with:

- General Information
- National Guidelines and Protocols
- Laboratory Personnel
- Laboratory Testing Services
- Quality Assurance
- Waste Management
- Logistics Management of Laboratory Supplies
- Equipment Availability and Maintenance
- Laboratory Infrastructure

The ATLAS is available in an electronic Access based format, as well paper based. Both approaches were used in this assessment. During interviews collected data was recorded on handwritten copies of the ATLAS and keyed simultaneously during the interview process on site

via a laptop. Data recorded on the hardcopy questionnaires where then reentered into another electronic ATLAS later that day. This data was then compared against the onsite electronicaly captured data to ensure concurrence with the site captured data (data validation process), and to ensure completeness and accuracy prior to including the data in the overall analysis. Data was collected daily from interviewers (hardcopy and electronic data) at the SCMS office in Bujumbura, reviewed and cleaned as necessary, and then aggregated. All data was then imported an analyzed using SPSS. Qualitative responses to open-ended questions were categorized and then also quantified. Data was sorted by level (Hospital and Health Center) and by PEPFAR versus Non-PEPFAR sites. If necessary, site level data can be further disaggregated and/or sorted for additional analysis as requested.

Site visits:

Fourteenteams were established to conduct the site visits and collect data using the ATLAS. Threesupervisory teams were also established to conduct spot checks during data collection visits. The STTA providers were part of the supervisory teams. All data collection and supervisor team members were trained on both tools (paper and electronic versions), as well as trained in collecting GPS (global positioning system) site location data.

Site visits were conducted over a four-day period. A complete data collection and supervisor visit schedule is included as Annex 2 in this report.

Results and Discussion

The Central/Intermediate Administrative Level Questionnaire was administered on August 14th in 4 groups, divided by areas of interviewee expertise and general knowledge of the laboratory network within Burundi. Interviewees included members of the National Reference Laboratory, MSPLS, NAC, DPML, and other site level staff. Interviewers included the STTA providers and SCMS country team members.A summary of the general findings are detailed in the following sections. Site level reports and additional data analysis are provided to further validate the central and intermediate administrative level findings, as well as to demonstrate service delivery point linkages and general implications, where possible.

Objective 1: Availability and implementation of national laboratory policies

As mentioned earlier, the laboratories in Burundi are classified under two levels, which comprise the Central Level (INSP) and the Peripheral Level (Hospitals – Public, Private and Confessional; Health Center labs [public, private, and confessional] and stand-alone private labs that provide only laboratory services). Laboratories at these different levels are supported by the Ministry of Public Health and Fight against AIDS, and various external donors. The overall network among laboratories across this tiered system is currently sub-optimal with significant issues associated with patient referral linkages.

Currently there is no specific national body responsible for formulating national laboratory policies within Burundi. In 2005, a preliminary framework for developing a national policy was established, but a finalized national laboratory policy document has yet to be completed and endorsed for national implementation. The existing framework does describe critical elements including human resources, administration, procurement, minimum health packages/services, lab techniques, validation and national prequalification of test kits for HIV and other STIs. There are also no written national guidelines on biosafety, post-exposure prophylaxis for HIV and Hepatitis B, as well as guidelines for disposal of damaged/expired laboratory products.

Additionally, there is currently no Laboratory Technical Working Group (LTWG) to coordinate national laboratory activities across different levels of the laboratory network, or to provide strategic programmatic direction, but committees are set-up for specific interventions when required.

Burundi currently does not have a policy on equipment standardization (harmonization). There are also limited directives for both internal and external quality assurance practices, which are

currently being implemented by INSP for six sites as part of the World Bank supported East African Public Health Laboratory Network project.

Without national policies, guidelines, and consistent technical leadership, sites have developed and implemented site-specific policies to assist in regulating laboratory service delivery and general practice. This leads to considerable variation in laboratory service delivery, quality of services, and general safety practices. As noted in Table 3, availability of such policies varies, with HCs reporting fewer documents to guide process and practice than hospitals. Without national standardsit is also important to highlight that the overall content and quality of the site-level specific guidelines and vary greatly.Additionally, the central level is not able to appropriately monitor and evaluate facility compliance, since a nationally established standard is not available.

Table 3: National Guidelines and Protocol Availability

% of sites reporting availability of guidelines and protocols	% Hospital (n=68)	% Health Center (n=51)	Average
Are guidelines and protocols for laboratory testing procedures available in this laboratory?	57.4	41.2	49.3
Laboratory infection control procedures?	49.8	37.7	43.8
Safe disposal of sharps (i.e., needles, etc.)	54.4	35.7	45.1
Safe disposal of biohazardous medical waste	48.3	31.6	40.0
Use of protective gear (PPE)	46.8	35.6	41.2
None available	5.6	8.2	6.9
Are written guidelines for post-exposure prophylaxis for hepatitis B available in this laboratory?	25	3.9	14.5
Are there written guidelines for disposal or destruction of damaged and/or expired products?	36.8	11.8	24.3
Are the national standard operating procedures (SOPs) available in this laboratory?	61.8	27.5	44.7

Infection control practices

Without national standardsand varied uptake of site-specific laboratory protocols associated with infection control practices, post-exposure prophylaxis for HIVand Hepatitis, and waste disposal, effective and consistent practice is limited. As captured, 49.8% of hospitals and 37.7% of HCs inteviewees reported thatinfection control procedures are in place, however, it is difficult to effectively and consistently ensure and execute such practices, if documented guidelines and the necessary commodities to ensure compliance are not available.

Adherence to sound infection control practices arecontigent on personal protective equipment (PPE) availability and constistent usage. To determine appropriate PPE availability and consumption, sites also provided estimated quarterly consumption and existing quantities of core personal protective equipment on hand. As noted in Table 4, soap, sharps containers, and gloves appear to be adequately utilized, but existing stock levels for soap and sharps containers (highlighted) far exceed quarterly usage rates by as much as four times the quarterly usage. Use of goggles (eye protection) and existing stock availability is limited, with no use of disposable aprons being reported for any sites. This clearly indicates inconstitent stock management and industry standard inventory control practices.

Table 4: Infection Control commodities

Average reported unit quantities consummed and on hand	**% Hospitals (n=68)**		**% Health Centers (n=51)**		**Average**	
	Average Quarterly Consumption	Quantities on hand	Average Quarterly Consumption	Quantities on hand	Average Quarterly Consumption	Quantities on hand
Hand soap	21.5	44.5	11.8	28.1	17.2	37.1
Unused sharps boxes	11.8	43.6	17.8	53.1	14.4	47.8
Gloves	334.0	132.6	261.6	160.2	299.6	145.1
Waste receptacle	1.3	3.7	1.5	1.6	1.4	2.8
Goggles	.1	.4	.0	.1	.0	.3
Mask	2.0	11.2	3.5	4.8	2.7	8.4
Apron (plastic)	.0	1.3	.0	.4	.0	.9
Laboratory coats	1.5	8.1	1.6	1.9	1.6	5.4

Staffing

When questioning sites about the existing staffing plan, there appears to be significant limitations of human capacity (Table 5). Overall, the results highlight that sites are significantly understaffed. This is commonly found in other medical specialities and across the health care system in Burundi. The staffing distribution across all hospitals and health center level sites (whether PEPFAR or non-PEPFAR supported) shows the relative scarcity of highly qualified laboratory personnel. Laboratory staffing levels range from 0.0 to 3.6 on average, for laboratory technicians at hospital levels. It was also found that refresher trainings are predominantly conducted for entry-level staff and are conducted more frequently at the health center level than at the hospital level facilities. Although clearly recognized as a significant challenge, laboratory HR issues are not

reflected in national planning, programming and budgeting exercises, thereby potentially hindering major strategic health systems strengthening efforts.

Appropriately trained and qualified laboratory personnel are needed to ensure well functioning laboratory systems that provide high quality, timely and reproducible results. Tiered networks of well-staffed laboratories are critical to providing a continuum of quality assured services that are essential for disease control activities. In light of this, a broader technical analysis including established data from the central level should be done detailing a comparison and variance measures against the national recommendations and existing HR levels to provide more guidance in terms of laboratory staffing trends and actual gaps that need to be addressed. Attempting to advance labstrengthening efforts could be potentially counter productive if staffing challenges are not properly addressed.

Table 5: Average number of reported staff by category

Average number of reported staff by category	Hospitals (n=68)		Health Centers (n=51)	
	Number of staff with this degree	Number who have attended refresher laboratoryrelated training course or workshop in the past 12 months	Number of staff with this degree	Number who have attended refresher laboratoryrelated training course or workshop in the past 12 months
Biologist-Pharmacist	0	0	0	0
Doctor-biologist	0	0	0	0
Scientific-biologist	0.1	0.1	0	0
Pharmacist	0	0	0	0
Family-doctor	0.1	0	0	0
Biotechnologist engineer	1.4	0.9	0	0
Laboratory technician	3.6	0.8	0.4	0.2
Nurse	0.3	0	0.6	0.2
Caretaker/Nurses Aide	0.6	0	0.4	0.2
Other laboratory workers	1.4	0.1	0.4	0.2

Supervision visits

Currently, there is no designated group to provide overall supportive supervision at each level of the laboratory network. The current practice across the health system and MSPLS reveals that supervision visits are very limited, and if conducted are program specific (TB, Malaria, HIV, STI). If funding is available at the central level, there appears to be motivation to organize supervision visits, but currently there is no anticipated budget or plan.

Self reports from interviewees, indicate that TB programmatic supervision visits are higher than other program areas, reaching 23.2% for hospitals, followed by HIV and Malaria at 17.3% to 12.3% respectively. STI supervision visits are limited. For existing supervision visits (summarized in Table 6), activities which are routinely observedare often limited to register examinations, number of tests performed, and a lab staff profile update. Currently, there is a standardized supervision checklist available for laboratory systems. Under general supply chain management and oversight, there currently is no mechanism to monitor the performance of the supply chain for laboratory reagents and consumables. These reported differences in the frequency of supervision visits might not represent an established national trend, but is more indicative of the impact of donor support on the different program areas that show a higher percentage of visits.

Although there is a supervision checklist available at the national/central level, there is no designated group and no guidelines for conducting overall site supportive supervision. In view of this, there is very little to no standardized documentation of feedback from visits conducted. Structured site supportive supervision is a critical component of the laboratory quality improvement process and needs to be addressed from the central level. There is a need to identify roles and individuals to perform the supervision, as well as define supervision tools that capture the needs of the country based on a national standard once established.

Table 6: Programmatic supervision visits

% of sites reporting supervision visits by disease area	% Hospitals (n=68)	% Health Centers (n=51)	Average
Malaria	12.3	17.1	14.7
STI	3.2	5.9	4.6
HIV/AIDS	17.3	16.8	17.1
TB	23.2	8.1	15.7
Other	1.2	9.2	5.2

Finance

It is unclear as to the national need and estimated funding gap to cover the requiredlaboratory supplies and equipment due the fact that a national laboratory quantification has never been conducted. GF (TB/HIV/Malaria) support is coordinated by the Country Coordination Mechanism (CCM), with additional oversight provided by the DPML for laboratory activities. The CCM is responsible for ensuring appropriate GF coordination, with USAID Burundi as a

voting member of the CCM. Committee Partenaires de Sante pour la Development (CPSD) is tasked with providing full oversight and overall coordination for laboratory related activities within Burundi, but it is unclear as to how well this organization functions in this role. It is unclear as to how financial resources are determined, prioritized and allocated to laboratories within this structured format, particularly when a laboratory strategic plan does not exist, as well as a national body responsible for formulating national laboratory policies and priorities.

Nationally there isn't a separate budgetary line item for laboratory services, provided funds are included under pharmaceutical services within the DPML budget. The United States Government (USG), GF (HIV, TB, and Malaria) and other donors do include separate budgetary line items for laboratory supplies (reagents and consumables), laboratory equipment and other pre-requisite and associated laboratory expenses.

Laboratory donor coverage includes:

- European Union (EU) – operating in 8 provinces
- USG PEPFAR– currently functioning in 4 provinces, with additional 4 moving into next year
- USG President's Malaria Initiative (PMI), national coverage for testing and bednets.
- GF – all 17 provinces, reimbursement model for services provided
- World Bank (WB) – funding and support soon to arrive (commodities, equipment, infrastructure, personnel)

Objective 2: Assessing the impact of existing supply chain processes

Laboratory commodities for all public health structures are managed through a centralized warehouse with procurement, quantification systems – called Central d'achat des medicaments au Burundi (CAMEBU). It is important to note that the STTA providers did not conduct a site visit to CAMEBU. Data/results are based on reports by program and central level laboratory staff.

CAMEBU is the central and sole unit responsible for supplying laboratory commodities to all lab facilities nation-wide. CAMEBU, with the support of the MSPLS does procure commodities, but a majority of commodity procurement is facilitated via program and other donor groups, which includes Global Fund, PEPFAR (SCMS and SIAPS), UNICEF and other stakeholders. Procurement is managed directly by the different national programs in accordance with systems unique to funding source requirements.

A central level store for laboratory supplies and equipment is available, but the TB program stores laboratory related commodities separately at their program office facilities. CAMEBU's

existing storage capacity is reported as being adequate to handle the current required quantities of laboratory supplies at the national level, yet the existing cold storage capacity is not adequate to handle the current quantities of cold chain reagents at the national store. The existing storage capacity (including cold chain) is not adequate to supportthe Government of Burundi's expanded program goals over the next three years. Refrigerated vehicles to distribute cold chain reagents do not exist, limiting the ability to transport critical cold chain products. There is an established distribution system for laboratory supplies and equipment for all levels, but there is not a sufficient number of functioning vehicles available to meet the distribution schedule at the each level (central and health district sites travel to CAMEBU to pick-up commodities).

Commodity transport was reported as a significant challenge for approximately 55% of hospitals and 10% of clinics, with vehicle availability and funding availability on aggregate reaching similar percent distributions respectively between hospitals and health centers. Of 95 reported comments by all those interviewed, 34 sites visited reported no existing issues associated with commodity vehicle transport, while 31 sites reporting the lack of a dedicated vehicle or vehicle maintenance issues. Others appear to not have a clear understanding of the commodity transport systems in place within their respective facilities (n=9), with 4 reporting cold chain adherence related issues.

Table 7: Transport of Laboratory Commodities		
% of sites report vehicle transport and funds for commodities	% Hospitals (n=68)	% Health Centers (n=51)
Does the facility have a vehicle to pick up the supplies?	54.4	9.8
Does the facility have the funds for fuel to pick up the supplies?	55.9	17.6

Inventory Control System

A nationally standardized laboratory logistics system does not exist within Burundi. The laboratories at all levels do not have nationally established minimum/maximum stock level requirements for reagents and laboratory consumables and the resupply quantity to fill orders is determined by the central level (CAMEBU). Reporting rates, frequency of reporting and methods for requesting commodities varies, with stock balances at all levels not being monitored regularly. The lack of a logistics system and general use of logistics standards is contributing to frequent stock outs and overstock situations.

Sites do report having established minimum/maximum stock level requirements, but national level representatives indicate that there are no national guidelines indicating required levels, or processes to establish required volumes. Emergency orders range from approximately one to

four per year, with an estimated arrival of 2 to 11 days, with health centers receiving orders significantly quicker than hospitals. Normal commodity orders were reported to take between approximately 1.5 and 3 months, with health centers again receiving products in approximately half the time of hospitals. Frequency of physical counts varying considerably between health centers and hospitals, averaging between 1.5 to 6.1 months respectively.

Table 8: Inventory Management - Stock availability and ordering			
	Hospitals (n=68)	Health Centers (n=51)	Average
Does the laboratory have a set minimum stock level for reagents and consumables at which orders need to be placed? (%)	69.1	49	59.1
Does the laboratory have a set maximum stock level for reagents and consumables above which the inventory level should not go? (%)	55.9	35.3	45.6
Percent of site that determine how much to order	2.5	3.1	2.8
Average days to receive order	11.3	4.4	7.9
In the last year, did you have an order that took longer than usual to fill? (yes - %)	39.7	25.5	32.6
How often is a physical inventory of reagents and consumable supplies conducted in the laboratory? (months)	5.3	3.1	4.2

There is currently no logistics information management system (LMIS) implemented within the national laboratory network. There are standard national reporting forms available, which are used to collect and report information on laboratory service delivery statistics. These forms assist in reporting national epidemiology statistics. These data sets are limited in utility and do not adequately reflect the necessary logistics data to effectively manage a national logistics system. Data usually remains at the site or facility level. Test estimates for HIV, Malaria, CD4 and other tests are reported in site registers that are not nationally standardized. Nationally standardized TB registers do exist and are used at site level. Unfortunately, there is no formal informatics system for data transmission, or requirements for sending data up to national levels.

Table 8 provides a detailed summary of general stock management practices. In general, stock management practices are varied across all levels. Overall, stock management tools and usage are split between stock cards and registers, and some other source of management tools (approximately 50%, 25%, and 25% respectively). Three methods for ordering products are noted (registers, forms, placing orders in some other fashion (examples: phone calls, email requests, and/or emergency or unplanned requests). To ensure stock availability and appropriate

stock management, standardization of stock management practices is necessary to improve commodity availability.Logistics data (consumption data) is used in a similar fashion across the network, with approximately 30% calculating commodity usage, 50% in calculating order quantities, and approximately 30% reporting transmitting data upstream. Standard test requisition form availability and usage varies across laboratories. Stock levels (49%), service statistics (100%), and surveillance (25%) data is routinely collected, but very little data is transmitted upstream, and it is unclear as to the final destination of such sent data.

Table 9: Logistics Management Information Systems - Summary of general supply chain management practices

Data represented as a % of sites reporting	Hospitals (n=68)	Health Centers (n=51)	Average
What type of forms does the laboratory use to keep track of reagents and consumables in stock?			
Stockcards	54.4	51	52.7
Ledgers	27.9	17.6	22.8
What type of forms does the laboratory use for ordering and receiving supplies?			
Order book	29.4	23.5	26.5
Delivery note	27.9	27.5	27.7
Requisition/Issue voucher	11.8	27.5	19.7
How is the information from the forms used?			
Calculate use of supplies	29.4	33.3	31.4
Calculateorderquantities	54.4	45.1	49.8
Report on use to the higher levels	30.9	29.4	30.2
Other	5.9	2	4.0
Does the laboratory have standard printed test requests and reporting forms?	79.4	23.5	51.5
Does this laboratory send reports on the following?			
Stock status	51.5	52.9	52.2
Lab tests performed	100	98	99.0
Surveillance reports	30.9	15.7	23.3
Where are these reports sent?			
To the central laboratory coordinator	1.5	7.8	4.7
To the regional laboratory coordinator	10.3	17.6	14.0
Is the logistics management information system integrated with the laboratory management information system?	29.4	17.6	23.5

Reporting

Overall, 87% of hospitals and 94% of health centersstate that logistic reportsare collated monthly. Although reporting does appear to be high, the final destination and overall systematic use of such data is unknown (Table 10).

Table 10. Frequency of logistic reporting

% of sites with reported frequency		% Hospitals (n=68)	% Health Centers (n=51)	Average
How often are these reports sent?	Monthly	86.6	94.1	90.4
	Bimonthly	0	2	1
	Quarterly	10.4	0	5.2
	Other	3	3.9	3.5

Stock levels

Commodity availability is a data driven process informed via stock on hand, average monthly consumption, as well as recording losses and adjustments. As noted earlier, methods of reporting stock availability, usage, and reporting frequencies varies between sites. To measure the impact of such variences,data was collected measuring the percent of sites reporting current stockout levels by testing area on the day of the site visit, as well as within the last 30 days. An abbreviated summary of commodities associated with TB, Malaria, and HIV- related testing components are detailed within Table 11.

During site visits Determine (screening) HIV test kit stockouts were reported at 10.3% of hospitals and at 7.4% for Stack Pack (confirmation), and 27.5% and 23.5% for health centers on the day of visit respectively. Stockouts within the past 30 days were reported higher in hospitals at 19.1% and 11.8% in hospitals, and reaching 31.4% and 19.6% at health centers.

During site visits chemistry safety tests for the monitoring of HIV drug toxicity were reported to be stocked out at approximately less than 10% of hospitals and double that for health centers (20%) on the day of the visit, with similar reports of stockouts within the past 30 days. Hospitals have significantly less reported stockouts (<5%) for general chemistries, andstockouts are becoming more regular for lipid profile tests (15-30%), and significantly more regular for amylase and lipase tests (13-20%).

CD4 reagent stockouts were reported at approximately 20% of sites, with an average of 18.7% being stocked out on the day of the visit, and 19.5% being reported as stocked out within the last 30 days.

Ziehl–Neelsen staining (TB screening, smear microscopy) stockouts were reported at 10.4% of hospitals, and at 11.9% within that past 30 days. Health centers reported higher rates at 24% and 22% respectively.

Table 11. Availability of sample reagents

	% Hospitals (n=68)		% Health Centers (n=51)		Average	
% of sites reporting stockout	Stockout on day of the visit	Stockout in the last 30 days	Stockout on day of the visit	Stockout in the last 30 days	Stockout on day of the visit	Stockout in the last 30 days
Determine HIV RTK	10.3	19.1	27.5	31.4	18.9	25.3
HIV STAT PAK Dipstick	7.4	11.8	23.5	19.6	15.5	15.7
Glucose	5.9	4.4	19.6	19.6	12.8	12.0
Creatinin	4.4	5.9	21.6	21.6	13.0	13.8
GOT/ASAT	4.4	4.4	21.6	21.6	13.0	13.0
GPT/ALAT	7.4	5.9	21.6	21.6	14.5	13.8
Cholesterol total	14.7	13.2	21.6	21.6	18.2	17.4
HDL Cholestrol	27.9	22.1	21.6	21.6	24.8	21.9
Triglyceride	16.2	13.2	21.6	21.6	18.9	17.4
Amylase	20.6	16.2	7.8	7.8	14.2	12.0
Lipase	16.4	13.4	5.9	5.9	11.2	9.7
CD4 reagent	19.4	20.9	18	18	18.7	19.5
ZN stain	10.4	11.9	24	22	17.2	17.0
Viral load reagent	16.7	15.2	4.1	4.1	10.4	9.7

Commodity storage:

Data analysis also included a detailed overview of written guideline availability regarding general laboratory storage requirements, with further details to include, appropriate flammable storage, first expired, first out (FEFO) adherence, consistent handling of damaged or expired products, product destruction, and cold chain monitoring (Table 12).

Laboratory product storage guidelines are limited at the site level, with 22.1% of hospitals, and 9.8% of health centers reporting written processes.Hazardous and flammable chemicals storage practices are varied, with 39.7% of hospitals and only 5.9% of health centersactually storing flammable and hazardous chemical appropriately.

Adherence to FEFO practices ranged from between 72.1% to 52.9% for hospital and health centrersvisited. Product seggragation compliance (damaged and/or expired products) ranged between 93% and 77% across all levels, with 93% to 71%meeting general guidelines for the disposal and/or destruction of damagedlaboratory products. Adherence to general cold chain practices varied considerably between hospitals and health centers, with hospitals achieving approximately 90% adherence, and 1/3 of health centers achieving cold chain adherence.

Table 12: Storage conditions

% of sites reporting 'Yes'	Hospital (n=68)	Health Center (n=51)	Total
Written guidelines for storing laboratory supplies according to their specifications (flammable, caustic, etc.) Exist. (Are Material Safety Data Sheets available?)	22.1	9.8	16.8
Flammable and hazardous chemicals are stored in specialized storage areas.	39.7	5.9	25.2
Reagents are stored according to the first-to-expire, first-out practice in the laboratory.	72.1	52.9	63.9
The laboratory makes it a practice to separate damaged and/or expired supplies from good products.	92.6	76.5	85.7
The laboratory makes it a practice to remove damaged and/or expired supplies from inventory	92.6	70.6	83.2
The laboratory makes it a practice to follow guidelines for disposal and/or destruction of damaged and/or expired laboratory supplies.	69.1	56.9	63.9
Cold chain items are always stored at appropriate temperatures.	91.2	33.3	66.4

Objective 3: Assessing the quality of services

To assess the overall quality of laboratory services anevaluation of service uptake was conducted by facility level. The general trend observed with service uptake is that most of the tests requiring high technical skills or use of sophisticated and/or automated equipment are done at the hospital levels only. When segregating and comparing the most frequent test offerings between hospital and health center sites, there is evidence of high uptake of routine tests such as HIV testing (97.1% - Hospitals and 78.4% - HCs), blood smear for haemoparasites [malaria] (92.6% - Hospitals and 94.1% - HCs), TB microscopy (66.2% - Hospitals and 13.7% - HCs),and stool examination of parasites (97.1% - Hospitals and 88.2% - HCs).

These high uptake testing levels observed with HIV, malaria, TB and stool analysis based tests at both hospital and health center levelscould be a reflection of the impact of the World Bank Performance Based Financing (PBF) project on service delivery and the impact of PEFPAR and GF contributions. There was significant low service uptake for viral load testing (4.4%) which is explained by the fact that viral load testing is done only at the National Institute of Public Health. For CD4 testing, the observed service uptake would be considered low in a HIV response strategy (47.1% at hospital level). Full blood count service uptake was observed to be at 79.7% in hospitals and only 2% at health center levels. Service uptake for the liver enzyme assays and other biochemistry-based tests are high (>80%), but are only performed at the hospital level, as would be expected. Service uptake for syphilis testing (77.9% and 3.9%) is significantly higher at hospitals compared to health center sites, which would be considered low as part of antenatal workups conducted at health centers.

In general, observational service uptake for different tests are influenced by the type of facility (government, faith-based or private), who is funding the program, equipment availability and whether the facility is based at the hospital or health center level. Some private/faith-based facilities at the health center levels are well equipped and well staffed with skilled technicians, and showed a wide range of services comparable with hospital level laboratories. In the complete analysis, this explains why some high level tests were observed within health center level laboratories.

For services not offered at the time of the visit, reasons were also provided as shown in Tables 15 and 16. Responses include: inadequate staffing, lack of commodities, instrument failure, lack of instrumentation, lack of training, and other.

Table 13: Tests Performed			
% of sites reporting test performance	% Hospitals (n=68)	% Health Centers (n=51)	Average
Hematology analyze	79.4	2	40.7
Sickle cell screen	35.3	0	17.7
Blood grouping/Rhesus typing	88.2	3.9	46.1
Blood slide for haemoparasites	92.6	94.1	93.4
Stool microscopy for parasites	97.1	88.2	92.7
HIV screening	97.1	78.4	87.8
Syphilis screening	77.9	3.9	40.9
Glucose	88.2	37.3	62.8
Creatinine	83.8	2	42.9
Transaminases (TGO/ASAT)	83.8	2	42.9
Transaminases (TGP/ALAT)	82.4	2	42.2
Cholesterol	76.5	0	38.3
HDL Cholesterol	52.9	0	26.5
Viral load	4.4	0	2.2
Malaria screening	20.6	0	10.3
Amylase	52.9	2	27.5
CD4count	47.1	0	23.6
TB Microscopy	66.2	13.7	40.0

Quality Control

As mentioned earlier in this report, there are no nationally instituted Quality Control or Quality Assurance policies, as well as general guidelines to assist in monitoring laboratory adherence, or to advocate for overall quality performance as part of a quality management system. There is no clear national standard associated with equipment calibration, lot to lot verification, post market surveillance, monitoring inter-lab variation, and External Quality Assurance (EQA) enrollment and monitoring.Self reports indicate that there is significant varied uptake of general quality control and there are various site specific policies. There apprears to be aslightly higher presence of site specific quality control related practices at hospital levels over health centers as expected, but an overall measure of approximately 25% coverage indicates how significant this deficiency actually is. The main tools used at site level for monitoring laboratory testing are registers, butagain these are not standardized. Additionally, the low level of laboratory staff at most facilities (as noted earlier) is a significant contributing factor towards implementing a quality management system, due to the effort required to monitor and perform at internationally

recognized standards.Without such systems there is a significant challenge in ensuring validity of the test results given out to patients.

Quality Assuranceis a key aspect of this evaluation, as is the importance of having national guidelines, staffing, supervision, service uptake, equipment maintenance, procurement and stock management, infrastructure and reporting standards. All of these elements must function appropriately and holistically to ensure delivery of high quality services. In order to achieve this, the government needs to build a realistic, reliable, measurable and sustainable Quality Improvement (QI) culture across the tiered system by ensuring;

- Leadership involvement and commitment to the process
- Define clear roles and responsibilities at different levels and for all stakeholders to ensure coherent functioning
- Build a good strategy to ensure implementation of a quality culture as this effort might be counter productive if no one is adhering to basic standards and gudelines.
- Strengthen workforce capacity and skills
- Identify, share and scale-up best practices

The difficult task is always establishing a place to start, but there is good will on behalf of Government of Burundi and interested donors – all of this will hopefully spark the much needed commitment that is needed to drive this process. As a first step, there may be an opportunity to standardize laboratory logbooks.

Table 14: Quality Assurance

% of sites reporting availability of QA policies and/or adherence	% Hospitals (n=68)	% Health Centers (n=51)	Average
Are there written quality assurance policies and procedures available in this laboratory?	25	23.5	24.3
Calibrate equipment daily, as indicated.	55.9	17.6	36.8
Check each batch of reagents using known positive and negative specimens?	54.4	13.7	34.1
Include commercially prepared controls whenever a batch of tests is run?	25	5.9	15.5
Countercheck test reports with another colleague before dispatch?	54.4	25.5	40.0
Does the laboratory participate in any external quality assurance scheme?	17.6	9.8	13.7

Additional Information Regarding Testing Uptake

To better understand why testing services may or may not be offered, sites were requested to categorize the main reasons for service interruption by test, and why a particular standard technique was not used. Responses were categorized by training, equipment availability, reagent stockout, staff availability, instrument failure, or other. Tables 15 and 16 provide an HIV based overview of hospital and health center responses.

A significant reported reason for not conducting a particular test appears to be due to lack of instrumentation. When averaging across all test offerrings, 54.1% of hospitals and 77.4% health centersreported a lack of laboratory diagnostic instrumentation as the main reason for inability to conduct testing. It is important to note, that CD4 testing at health centers is not widely available, therefore these reports are high, since these services would not be expected to be conducted at the health center level. Reagent availability on average was reported at 23.3% and 25.9% of hospital and health centers respectively. Availability of appropriate staff constituted concerns for an average of 19.1% of health centers,but only 5.1% at hospitals, with lack of adequately trained staff reaching an average of 21.1% at health centers and 7.2% of hospitals. Instrument failure was only reported at 1.5% of hospitals and 0.4% of participating health centers.

Table 15: Reason(s) for not using the standard technique or for not doing the test

	Hospitals (n=68)					
	Not trained in the technique	Equipment not available	Reagent not available	No adequate staff to perform the technique	Equipment not working	Other
Haematology	0	60.9	13	0	0	34.8
HIV screening	20	60	40	20	0	20
Glucose	7.1	85.7	14.3	7.1	0	0
Creatinine	6.7	80	20	6.7	0	6.7
GOT/ASAT	4.8	61.9	14.3	4.8	0	28.6
GPT/ALAT	8.7	56.5	13	4.3	0	30.4
Cholesterol total	4.5	59.1	18.2	4.5	0	27.3
HDL Cholesterol	6.3	40.6	37.5	3.1	3.1	18.8
Triglycerides	4.2	58.3	20.8	4.2	0	25
Viral load	48.6	74.3	40	22.9	0	5.7
CD4 count	7.1	35.7	14.3	0	14.3	35.7
Average	7.2	54.1	23.3	5.1	1.5	26.7

Table 16: Reason(s) for not using the standard technique or for not doing the test						
	Health Centers (n=51)					
	Not trained in the technique	Equipment not available	Reagent not available	No adequate staff to perform the	Equipment not working	Other
HIV rapid tests	15.4	46.2	30.8	15.4	0	15.4
CD4 Numeration	27.3	63.6	9.1	9.1	0	0
Average	21.2	77.4	25.9	19	0.4	2.9

HIV testing algorithm

As noted following a joint PEPFAR - USAID, DoD, OGAC HTC visit conducted in July 2013, the currently practiced testing algorithm aligns more closely with the WHO's recommendations for algorithms in countries with prevalence rates <5%. With a general HIV prevalence of 1.4% (DHS, 2010) the newly proposed (three test/tie breaker) testing algorithm is in fact not recommended for the Burundi epidemic. Currently, the propsed third rapid HIV test (tiebreaker) is still under evaluation at INSP before national implementation can begin, however, given the recommendations and discussions with national technical working groups, this may no longer be a concern. The currently proposed algorithm would not be recommended as defined by WHO, and in Burundi's case, using it could result in increased false positive results.

Objective 4. Assessing equipment maintenance

Laboratory maintenance is a risk management practice used to maximize the delivery of critical laboratory services and minimize the overall impact of instrument downtime, commodity loss, and wastage. Developing a successful maintenance approach requires a complete understanding of diagnostic coverage, existing contractual agreements for services, active warranty coverage, equipment failure types and overall maintenance management and vendor monitoring practices. Until there is an evidence-based understanding established regarding why, how, and when equipment fails, establishing an informed strategy to extend and maximize service and performance of laboratory instruments can be difficult.

A number of general observations can be made about the national laboratory equipment maintenance strategies based on SCMS's own experience over the past few years:

- Renewal of contracts takes about 8- 12 weeks and tends to be easier with the larger vendors of "closed" systems when compared to those of smaller, "open" systems.
- Maintenance agreements are many times negotiated on an instrument-by-instrument basis, resulting in a heavy administrative burden. This approach also fails to take advantage of economies of scale. This also makes comparisons between maintenance contract terms as well as monitoring of contract and vendor performance quite difficult.
- Adherence to contracts is not normally monitored, nor is vendor performance or compliance with contractual obligations.
- There is limited capacity and consistency in approaches to managing maintenance contracts. There is also a lack of contract management capacity among procurement professionals, along with a parallel lack of laboratory maintenance technical knowledge by contract professionals. This results in challenges in the timely and effective implementation of laboratory maintenance agreements.
- Serious contract management issues include price inconsistencies, and the term limitations with donor support and financing.
- There is limited capacity and existing staff are not well versed in the complex world of contract language.
- Information regarding the condition of existing instruments and service history can be difficult to obtain.
- There are numerous incidents of "out-of-service" equipment, and a frequent lack of backup testing capacity. In addition, there is no consistent method in place to

track these incidents. The result is a disruption in the national testing services which means underutilization of testing capacity that is likely to lead to the underestimation of national HIV treatment targets. This in turn results in distortion of the commodity supply projections/quantifications used for HIV care and treatment program planning.

- Lack of standardization (harmonization) within an individual country is a serious challenge to establishing more effective longer-term maintenance agreements.
- In general, the reasons and types of "out-of-service" equipment are not well documented or reported. Currently, laboratory equipment vendors are the most reliable source of information for documenting out-of-service equipment trends. In addition, as the aggregation of maintenance and service data is not done, a broader identification of non-functioning equipment and related trends is not currently possible.

Equipment failure can be defined as the point when the equipment no longer delivers the minimum service that is expected of it. It may not yet be fully inoperable, but it may not be able to deliver the quality of diagnostic services that are expected.

In general equipment failure may be caused by one of the following common factors:

- Inadequate laboratory environment (AC, humidity control, direct sunlight, etc.)
- Inadequate preventative maintenance
- Inadequate technical training or no available technicians
- Lack of adherence to SOPs and control processes
- Over-stressed components due to high patient loads and diagnostic demands
- Poor reagent quality – improper storage, product degradation
- Poor instrument design or component quality

During the Burundi laboratory assessment it is clear that the use of and presence of instrument maintenance schedules, registers, and SOPs to address instrument maintenance and response to instrument failures is varied and often not practiced. In general, there is a higher presence of noted documentation at hospital levels over health centers, but these would constitute site level approaches. Health centers generally have minimal equipment to maintain, therefore maintaince standards are less prevelant. Again, as note earlier in this report, there is no clear national standards associated with maintenance practices and no direct leadership body providing

oversight of such activities. It is important to recognize that many laboratory-based instruments, particularly diagnostic instrumentation are supported via third party vendor contracts for ongoing maintenance and support. By coordinating a national oversight group responsible for leadership in this area there is an opportunity to establish national maintenance contracts and achieve economies of scale to achieve improved service and maintenance outcomes with existing vendors.

Table 17: Equipment Availability and Maintenance			
% of sites reporting availability of records and/or adherence to maintenance standards	% Hospitals (n=68)	% Health Centers (n=51)	Average
Is the equipment in this laboratory standardized (similar to the equipment found in the same level laboratories), as recommended by the central level?	57.4	37.3	47.4
Do you have a maintenance schedule for the equipment, other than daily cleaning?	45.6	2	23.8
Do you have a maintenance record?	52.9	5.9	29.4
Do you routinely maintain records of refrigerator/freezer temperatures?	63.2	9.8	36.5

Table 18 provides an abbreviated list of equipment and laboratory instruments of interest in relation to HIV treatment programs that were identified as operational or non-operational during the day of the visit. Duration of instrument or equipment failure was not collected.Core items listed are specifically related to autoclaving, refridgeration, CD4, biochemistry, hematology, and viral load and EID (PCR based) equipment and instrumentation.

Overall, reported instrument operational rates a very good, with areas of concern highlighted. Health center operational rates are very high, but as noted earlier, instrument and equipment needs within health center a generally very limited. As expected, hospitals do have higher rates of instrument failures, with operational rates ranging from 40% (2 of 5) for ELISA instrumentation, with 75% for biochemistry, to almost 100% for CD4, viral load and EID instrumentation. With limited instrument coverage within Burundi, particularly with viral load and EID, extended instrument failures would significantly impact treatment regiment transitions and PMTCT programs. Of particular concern would be microscope functionality, with 80% at hospitals, and only 63% of microscopes being operational at health centers. These rates would have a significant impact on service delivery associated with TB and Malaria screening, as well as additional hematological and parasite work-ups.

Table 18. Equipment availability	Distribution (%)		Hospitals (n=68)			Health Centers (n=51)			Total		
Total amount of equipment and % operational	Hospitals	Health Center	Number available	Number functioning	% Operational	Number available	Number functioning	% Operational	Number available	Number functioning	% Operational
Anaerobic jars	33%	67%	2	2	100%	4	4	100%	6	6	100%
Autoclave (fixed)	86%	14%	12	9	75%	2	2	100%	14	11	79%
Microtome disposable blade	50%	50%	2	2	100%	2	2	100%	4	4	100%
Automatic micro pipettes	89%	11%	355	312	88%	42	39	93%	397	351	88%
Automatic tissue processor	0%	100%	0	0	0%	2	2	100%	2	2	100%
Chemistry auto analyzer or photometer	88%	12%	30	25	83%	4	4	100%	34	29	85%
Deep freezer (-20° C)	60%	40%	3	2	67%	2	2	100%	5	4	80%
Desktop computer and printer (office)	92%	8%	34	34	100%	3	3	100%	37	37	100%
Differential counter	50%	50%	2	1	50%	2	2	100%	4	3	75%
Electric digital balance	93%	7%	26	21	81%	2	2	100%	28	23	82%
Electrophoresis system	50%	50%	2	1	50%	2	2	100%	4	3	75%
ELISA reader and washer	71%	29%	5	2	40%	2	2	100%	7	4	57%
Flow cytometer CD4	100%	0%	23	21	91%	0	0	0%	23	21	91%
Viral load instrument	100%	0%	1	1	100%	0	0	0%	1	1	100%
Hematology auto-analyzer	92%	8%	68	64	94%	6	5	83%	74	69	93%
Spectrophotometer	94%	6%	93	80	86%	6	5	83%	99	85	86%

Infrastructure:

A complete assessment of existing infrastructure was also conducted, with a complete summary detailed in the following table (Table 19: Infrastructure).General considerations included adequate space and general condition, security, storage, water, electricity, waste disposal (incinerator), ventilation, laboratory furniture, lavatories, and safety equipment (fire exstinguishers).

Table 19: Infrastructure

% of sites reporting 'yes'	% Hospitals (n=68)	% Health Centers (n=51)
Laboratory area is maintained in good condition (e.g., clean, all trash removed, shelves are sturdy, etc.)	88.2	70.6
Laboratory is secured with a lock and key but is accessible during normal working hours.	94.1	90.2
Laboratory has shelves and lockable cupboards; access is limited to authorized personnel.	63.2	33.3
Laboratory has sufficient space to adequately store existing supplies.	50.0	43.1
Laboratory has running water	88.2	60.8
Laboratory has access to filtered rainwater	20.6	15.7
Laboratory has a consistent power supply and/or a generator with a guaranteed supply of petrol or solar power.	94.1	62.7
Laboratory has an adequate number of power points (sockets).	95.6	45.1
Laboratory has separate sinks for washing laboratory ware and staining, and for washing hands after being exposed to infected materials.	58.8	9.8
Laboratory has drainage from laboratory sinks that are closed and that lead to either a septic tank or deep pit.	95.6	62.7
Laboratory has a **functioning** incinerator or other nationally acceptable waste management (e.g., a protected pit) to correctly dispose of all hazardous waste (e.g., needles, toxic materials) and fuel for the incinerator (if applicable).	89.7	86.3
Laboratory floors are in good condition without the need for repair.	86.8	82.4
At all times, roof is maintained in good condition to avoid sunlight penetration.	94.1	88.2

Internal walls are in good condition without the need for repair.	91.2	82.4
External walls are in good condition without the need for repair.	92.6	82.4
Laboratory is well lit.	92.6	74.5
Laboratory is well ventilated and cross-ventilated	79.4	70.6
Windows and doors are in good condition without the need for replacement or repair.	92.6	76.5
Laboratory has firm built-in benches with leveled tops in good condition.	57.4	41.2
Laboratory has firm shelves to store supplies and reagents.	57.4	37.3
There is adequate glassware and/or plastic ware	69.1	19.6
Distilled/deionized water is available.	66.2	9.8
Windows have security bars.	85.3	78.4
There is an adequate number of laboratory stools	66.2	49.0
The laboratory has an indoor patient waiting area with seats.	36.8	19.6
Lab staff have access to clean toilet facilities	63.2	56.9
Lab staff have access to safe drinking water supply.	48.5	39.2
Laboratory has a working fire extinguisher	22.1	5.9

Recommendations

After conducting site visits and a thorough review of collected assessment data, the laboratory assessment TA providers established general recommendations based on national oversight, guideline availability, operational laboratory supply chain and additional challenges that became apparent during the assessment process. As part of "*Objective 5: Determining recommendations for the establishment of efficient lab networks throughout the country,"* the following recommendations were developed in response to those identified challenges and include the following:

1. **National laboratory policies:**

- There is a need to establish a Laboratory Technical Working Group (LTWG) to coordinate national laboratory activities across different levels of the laboratory network, and to provide strategic programmatic direction.

- The established technical working group (TWG) should lead and serve as the responsible group for developing national laboratory policies and a national strategic plan on behalf of the MOH.
    - The MOH ultimately endorses and executes the recommended policy measures. This effort can build on the initial 2005 preliminary framework for developing a national policy. The existing framework does describe critical key elements including human resources, administration, procurement, minimum health packages/services, lab techniques, validation and national prequalification of test kits for HIV and other STIs. There is also a need to ensure nationally endorsed guidelines on biosafety, post-exposure prophylaxis for HIV and Hepatitis B, as well as guidelines for disposal of damaged/expired laboratory products. Additional policy guidelines are required for data management and usage, stock management and storage, and ensuring quality assurance measures and site supervision and mentoring.

- Identify and develop immediate, short, and long term implementation strategy (way-forward plan) to address existing challenges as part of the national strategic plan. This plan should be developed by the established TWG.

- Burundi should seek to advance a national laboratory harmonization strategy that will define minimum test offerings by level, defined methodologies, instrument types and coverage, as well as staffing complement. Harmonization and standardizing laboratory testing services can directly improve the availability of laboratory reagents

and consumables by reducing the variability in commodity requirements, therefore enhancing laboratory quantification forecasting efforts.

- With larger volumes of fewer products, programs can effectively negotiate pricing and instrument service contracts leveraging economies of scale. With limited stock variability, stock can be redistributed between facilities to correct stock imbalances, thereby reducing the risk of stockouts and further wastage, enhancing commodity consumption efficiencies. Standardization also benefits the overall management of the laboratory network by enhancing the ability to predict need, allowing for the rational allocation of resources and systematic planning for the scale up of services. Efforts can be made to streamline maintenance strategies with limited instrument diversity. In terms of managing human resources, standardization achieves greater efficiency in training and management of staff due to standardized testing techniques used at each level of the system. Harmonization and standardization also supports the development of enhanced quality assurance programs because it reduces the overall impact of inter laboratory variation across facilities, increasing the reliability and consistency of test results and reducing overall cost associated with external quality assurance (EQA) schemes, including proficiency testing (PT) programs.

- CPSD and technical and financial partners involved could assist with review, orientation, and next steps from the findings of this report, if their TOR would allow this… If the CPSD cannot serve in this capacity another designated body within the MOH (laboratory directorate) should ensure appropriate donor coordination for laboratory development support. This body will ensure strategic alignment of donors to the nationally developed strategic plan for laboratory, leverage donor funding to maximize ROI, strategic technical support (CDC, EAPHLN, ASLM, others), as well as ensuring compliance to established national guidelines and goals. Current donor coverage includes:

    - EU – operating in 8 provinces
    - PEPFAR – currently functioning in 4 provinces, with additional 4 moving into next year
    - GF – all 17 provinces, reimbursement model for services provided
    - WB – funding and support soon to arrive (commodities, equipment, infrastructure, personnel)

- Currently, INSP has developed its own mandate (development of laboratory guidelines, QC, EQA and Proficiency Testing oversight, and standardization of SOPs, but this mandate must be formally endorsed and implemented.

- There is a need to gain further visibility into funding priorities and identifying existing funding gaps.
    - Nationally there isn't a separate budgetary line item for laboratory services, it is currently included under pharmaceutical services.To sustain lab policies and strengthen the laboratory portfolio within the national health system, Burundi should seriously consider the creation of a separate directorate for laboratory services.

- A broader technical analysis could be done detailing comparison and variance measures against the national recommendations and existing HR levels within the health sector to provide more guidance in terms of laboratory staffing trends and actual gaps that need to be addressed. Attempting to advance lab strengthening efforts could be potentially counter productive if staffing challenges are not properly addressed.To strengthen competent-based laboratory workforce, licensure, and regulatory bodies in Burundi, the government should consider establishing the Burundi Bureau of Standards (BBS)

2. Supply chain processes and practices

- As mentioned under the policy recommendations, supply chain policy and guidelines are required for data management and usage, stock management, distribution and storage, and ensuring quality assurance measures, site supervision and mentoring in relation to supply chain practices.
- Due to the lack of a formalized logistic system for laboratory based commodities a system design and implementation strategy should be developed. This would include areas of LMIS, inventory control systems, report and requisitions, data management and reporting, transporation, M&E, training and supervision, and warehousing and distribution. Refer to the 2011Burundi Supply Chain Assessment for HIV Commodities for additional information.
- A national Laboratory Quantification should be conducted to quantify actual commodity demands and funding needs, as well as funding gaps to identify national priorities in programmatic scale-up and to address existing challenges.
- As mentioned earlier, Burundi should seek to advance a national laboratory harmonization strategy. Refer to national laboratory policy recommendations.

3. Quality of services

- As mentioned under the policy recommendations, a quality improvement (QI) plan must be developed. This would include policy and guidelines for data management and ensuring quality assurance measures, site supervision, as well as mentoring in relation to international quality assurance practices.
- Consider implementing a quarterly supportive supervision and mentoring system for all sites. Several countries are moving to a model of quarterly site visits, wherein staff from the MOH, the District Health Office and, where appropriate, implementing partners, meet with clinic staff, tour the facility, review logs and registers and commodity supplies, and assess the quality of services being provided.
- Accreditation – in partnership with ASLM, CDC, EAPHLN –Ensure support for INSP to reach ISO accreditation through the WHO-AFRO step wise process and leverage knowledge of sites (6 sites in relation to WB funding support) enrolled in the SLIPTA process to serve as potential mentors in supporting additional laboratory network sites to build capacity to improve the quality of laboratory services offered.
- There is a need to standardize laboratory log books, test requisition forms and implement EQA for HIV rapid testing using DTS. This will enable facilities to better monitor the quality of their procedures and report to the district and national level with these statistics. For example: The HIV rapid test logbook should include inputs such as lot numbers, person performing test, and expiration dates (see WHO HTC Quality Improvement Handbook, 2011).
- The delayed roll-out of the new HIV algorithm also provides an opportunity to re-assess the newly proposed algorithm to a low prevalence algorithm to avoid high false positive rates.

4. Equipment maintenance

- Again, Burundi should seek to advance a national laboratory harmonization strategy. This would assist in guiding instrument coverage and seek to reduce instrument diversity in an attempt to create efficiencies in instrument training demands, eliminate excessive commodity demands, and create economies of scale in relation to maintenance strategy development, and end of life replacement strategies.
- Implement the SCMS 12 question instrument justification approach to ensure evidence based instrument procurement and placement strategies to guide future instrument procurements. The 12 question justification approach is provided as an annex to this report.

Conclusion

The most significant challenge identified as an outcome of this assessment is that Burundi lacks an endorsed and implemented national laboratory policy, strategic plan, and nationally endorsed guidelines in respect to human resource planning, overall administration, coordination, procurement, minimum health packages/services, and standardized laboratory practices and techniques. A preliminary framework for developing a national policy was established back in 2005, but a finalized national laboratory policy document has yet to be completed and endorsed for national implementation. In response, laboratories have developed and implemented site-specific policies to assist in regulating laboratory service delivery and general practice. Although commendable at the site level, this has led to considerable variation in laboratory service delivery practices, quality of services, and general saftety practices.

To address the existing challenges detailed within this report, a national laboratory TWG should be established as soon as possible to develop an immediate, short, and a long term implementation strategy (way-forward plan). This group should serve as the responsible group for developing national laboratory policies and a national strategic plan on behalf of the MOH. Constituents should be varied, and include clinicians, laboratorians, donors, implementing partners, and key leaders that can advocate for laboratory development and ensure the coordination of stakeholders and donors. The overall aim of this group should be to serve the interests of the Government of Burundi and their overall stake in responding to the health demands of the populations their laboratory services are aimed to serve.

Annex1. ATLAS questionnaire

For more information, please visit www.deliver.jsi.com.

Annex2. Site visit schedule

	BUBANZA Province	Data collector team	Supervisor team
Wednesday 14	GIHANGA Hosp	Team V	Team III
	MUDUBUGU Hosp		
	GARUKIRA MUSENYI HC		
	MPANDA Hosp	Team XII	
	BDS MPANDA		
	BUBANZA Hosp	Team III	
	DAGROUPAS AMAGARA NI IKINDI HC		
	CONFIANCE HC		
	BUJUMBURA City	**Data collector team**	**Supervisor team**
	INSP (NRL)	Team I	Team I
	HPRC Hosp		
	MISERCORDE Clinic	Team II	
	CPLR Hosp		
	SANIT JEAN Clinic		
	CMCK Hosp	Team VI	
	BUMEREC Hosp		
	NKORINEZA HC		
	CLINIQUE CEZAR Clinic	Team VII	
	HMK Hosp		
	NTASEKA HC		
	CNPK Clinic	Team IX	
	CHUK Hosp		
	MUNEZERO HC		

BUJUMBURA City	Data collector team	Supervisor team
POLYCEB Clinic	Team X	Team I
SAINT MARC Clinic		
NEW HOSPITAL Clinic		
BATWENGA Clinic	Team XI	
BUJUMBURA CENTRE HD		
MAISON MEDICALE Clinic		

RURAL BUUJUMURA	Data collector team	Supervisor team
SPD TENGA HC	Team VIII	Team II
IZERE HC		
RUSHUBI Hosp	Team XIII	
RUSHUBI HD		
KABEZI Hosp	Team XIV	
MAGARA II HC		
CURGO Hosp		
GWIBAGA Hosp	Team IV	
IJENDA Hosp		

	KAYANZA province	Data collector team	Supervisor team
Friday 16	GATARA HC	Team I	Team I
	BANGA HC		
	KAYANZA Hosp		
	MUSEMA Hosp	Team II	
	MUSEMA HD		
	GAHOMBO HC	Team III	
	GAHOMBO Hosp		
	SWAA KAYANZA		
	MWARO Province	**Data collector team**	**Supervisor team**
	SANATORIUM	Team IV	Team II
	KIBUMBU HC		
	KIBUMBU Hosp		
		Team V	
	BUZIRACANDA HC		
	FOTA Hosp		
	FOTA HD		
	CIBITOKE Province	**Data collector team**	**Supervisor team**
	NGOMA HC	Team VI	Team III
	CIBITOKE HD		
	MUGWI HC	Team VII	
	CIBITOKE Hosp		

CIBITOKE Province	Data collector team	Supervisor team
NYABUGIMBU HC	Team VIII	Team III
MABAYI Hosp		
MURAMVYA	**Data collector team**	**Supervisor team**
KIGANDA HD	Team IX	Team I
KIGANDA Hosp		
GATABO HC	Team X	
MUNANIRA HC		
MURANVYA Hosp	Team XI	
NYARUCAMO HC		

BURURI Province	Data collector team	Supervisor team
RUTOVU Hosp	Team XII	Team II
NEMA HC		
MATANA Hosp		
UNITE DE SOINS HC	Team XIII	
BURURI HD		
BURURI Hosp		
RUMONGE Hosp	Team XIV	
KIGWENA II HC		

	KIRUNDO Province	Data collector team	Supervisor team
Monday 19	MUKENKE Hosp	Team I	Team I
	NYAGISOZI HC		
	BUSONI HD		
	IZERE HC	Team II	
	KIRUNDO Hosp		
	MURAMBA HC		
	MUYINGA Province	**Data collector team**	**Supervisor team**
	MUGANO Hosp	Team III	Team I
	RABIRO HC		
	MUYINGA Hosp	Team IV	
	NYARUNAZI HC		
	ABUBEF		
	GASHOHO Hosp	Team V	
	MUYINGA HD		
	CANKUZO Province	**Data collector team**	**Supervisor team**
	CANKUZO Hosp	Team VI	Team II
	MUREHE HC		
	MURORE Hosp	Team VII	
	CAMAZI HC		
	NYURO HC	Team VIII	
	MURORE HD		

	RUYIGI Province	Data collector team	Supervisor team
	BUTEZI Hosp	Team IX	Team II
	NYANKANDA HC		
	GISURU Hosp		
	KINYINYA Hosp	Team X	
	KINYINYA HC	Team XI	
	KINYINYA HD		
	RUYIGI Hosp	Team XII	
	REMA Hosp		
	BISINDE HC		
	RUTANA Province	**Data collector team**	**Supervisor team**
	GIHOFI Hosp	Team XIII	Team III
	BUTARE HC		
	MERE DE LA MISERCORDE HC		
	MAKAMBA Province		
	MIRUKIRO HC	Team XIV	
	MAKAMBA Hosp		
	TURISANZE HC		

	NGOZI Province	Data collector team	Supervisor team
Tuesday 20	MUSENYI ETAT HC	Team I	Team I
	RUHORORO HC		
	KIREMBA Hosp	Team II	
	KIREMBA HD		
	BUYE Hosp	Team III	
	MIVO Hosp		
	ANSS NGOZI	Team IV	
	NGOZI Hosp		
	ABUBEF NGOZI		
	GITEGA Province	**Data collector team**	**Supervisor team**
	GITEGA Hosp	Team V	Team II
	VISION SANTE HC		
	SWAA GITEGA		
	MUTAHO Hosp	Team VI	
	KIBIMBA Hosp		
	MOTOYI Hosp	Team VII	
	KIRIMBI HC		
	NTITA Hosp	Team VIII	
	RYANSORO HD		
	CLINIQUE SONGA Clinic	Team IX	
	NYARURAMBI HC		
	KIBUYE Hosp	Team XII	
	MUGARURO HC		

RUTANA Province	Data collector team	Supervisor team
RUTANA Hosp	Team XIII	Team III
MUSONGATI Hosp		
DISTRICT RUTANA		
MAKAMBA Province		
	Team XIV	
NYANZA-LAC Hosp		
MUKUNGU HC		
NYANZA-LAC HD		

KARUSI Province	Data collector team	Supervisor team
BUHIGA Hosp	Team X	Team II
NTUNDA HC		
BUHIGA HD	Team XI	
MASABO HC		

	NGOZI Province	Data collector team	Supervisor team
Tuesday 20	MUSENYI ETAT HC	Team I	Team I
	RUHORORO HC		
	KIREMBAHosp	Team II	
	KIREMBA HD		
	BUYEHosp	Team III	
	MIVOHosp		
	ANSS NGOZI	Team IV	
	NGOZIHosp		
	ABUBEF NGOZI		
	GITEGA Province	**Data collector team**	**Supervisor team**
	GITEGAHosp	Team V	Team II
	VISION SANTE HC		
	SWAA GITEGA		
	MUTAHOHosp	Team VI	
	KIBIMBAHosp		
	MOTOYIHosp	Team VII	
	KIRIMBIHosp		
	NTITAHosp	Team VIII	
	RYANSORO HC		
	CLINIQUE SONGA	Team IX	
	NYARURAMBI HC		
	KIBUYEHosp	Team XII	
	MUGARURO HC		

RUTANA Province	Data collector team	Supervisor team
RUTANAHosp	Team XIII	Team III
MUSONGATIHosp		
RUTANA HD		
MAKAMBA Province		
NYANZA-LACHosp	Team XIV	
MUKUNGU HC		
NYANZA-LAC HD		
KARUSI Province	**Data collector team**	**Supervisor team**
BUHIGAHosp	Team X	Team II
NTUNDA HC		
BUHIGA HD	Team XI	
MASABO HC		

Annex3. SCMS 12 question instrument procurement justification

Question		Possible Data Source	Comments
1.	Is the diagnostic instrument on the nationally approved instrument list?	Ministry of Health list of instruments or in the laboratory service strategic plan or health sector strategic plan	In most countries, there exists at least the National Health Sector Strategic Plan that will incorporate components of instrument allocation by levels of health care. However, many countries do not have a laboratory sector strengtheningcomponent as part of their strategy.
2.	Is the request to replace existing old instruments? If yes, is there an instrument replacement strategy?	Deployment strategic document from the requesting client.	It is important to look at the need of proposed sites, the work load and whether or not they already have a similar instrument. If the same type is requested, additional planning for commodities is not required.
3.	If these instruments are for new locations, is there an instrument deployment plan for the proposed instruments?	Instrument deployment plan from the requesting agency.	As indicated in 2 above, the requesting agency must have a plan to indicate where the instruments are to be deployed. This is important in negotiating the terms of the instrument purchase to include installation and training. If for a new site, additional planning and funding may be required for additional commodity volumes.
4.	What is the current estimated diagnostic capacity for this particular instrument type in country?	MOH Quantification data. Manufacturer's User Guide.	This can be estimated using the instrument capacity and estimated testing demand to determine existing instrument coverage utilization. Example. Formula for utilization = test numbers performed on the type of machine, divided by maximum throughput of the machines. If you have 2 test per day on 1 FACS Count with a throughput of 50 tests per day, yourareat 4% capacity.
5.	What is the diagnostic	MOH Quantification data,	Determine the burden or demand of

	burden at the proposed sites? Is the instrument selected appropriate, based on instrument capacity vs. diagnostic demand?	service capacity data, number of patients in the proposed sites,	that particular test for that site. Example, if it is CD4 instrument, how many patients are on ART at this site, how many are on care, how many CD4s are likely to be produced from this site per day, per month or per annum? Ensure that instrument capacity is appropriate for site demand.
6.	Is there suitable infrastructure at the proposed sites - any additional peripheral needs?	Manufacturer's Instrument Specification.	Most instruments are sold alone without the combination of other peripheral requirement for installation. For example, if you are buying GeneXpert that requires temperature controls, does the site having the right temperature control peripherals for this machine? If you are buying FACS Count, do you have the specific UPS for this machine? If you are buying PIMA, have you included the control cartridge kit?
7.	Is there expected service delivery expansion at the proposed sites? (scale up)	MOH strategic plan, partner supported plan, client scale up plan.	In some cases, the diagnostics burden of the proposed sites (Q5) may not be adequate now, but there is a plan to expand the diagnostic uptake at the proposed sites. For example, the site is to be upgraded from a health center clinic to a level 1 referral facility in the next 6 – 12 months. This may change the type of instrument to procure for this site.
8.	Have the additional costs of reagents, staff training, maintenance been considered - what are the funding sources and estimated costs?	Workplan budget, MOH roll out plans, CDC or any partner client	No instrument should be purchased without consideration of training and maintenance. Most manufacturers and vendors will have this option when purchasing an instrument. It may be important to investigate any existing contracts associated to your intended instrument before discussions. If there is none, do you have a budget to separately buy this option?
9.	Will instrument require Preventive	Several data sources – MOH, vendors, clients, partners,	Most instruments come with a 1-year limited warranty. However,

	Maintenance Service (also called an Extended Warranty) after its warranty expires?	funding agency etc.	once this warranty expires the instrument is left without maintenance. It is important to consider the existing maintenance agreement in the country and who is/are responsible for funding and managing the contract.
10.	Is a local Authorized Manufacturer Distributor available to service the instrument?	Manufacturer, vendor or MOH	For a country to have maximum benefit from their instrument there should be an existing authorized manufacturer's representative in the country. If they are, do they have the right caliber and number of service engineers for the existing machine? Would they be able to handle additional machines at the current rate? How are they performing now? Are they providing cost effective support for instruments? Will they provide similar support for your new additions?
11.	Is there a Maintenance Service Agreement (MSA) in place for similar instruments you have on-hand? If yes, is the MSA still valid and who is managing the Agreement?	Same as Q9	Similar to Q9, what is the existing maintenance agreement for this type of instrument? Who is the responsible party for this instrument? Do you have the buy-in from this agency to tap into this instrument contract or do you plan to purchase a new contract for your machines only? Remember, the more machines under a contract, there are possibilities to gain economies of scale.
12.	Is an equipment inventory list available for similar instruments on-hand? If so, was an inventory conducted in the past 12 months with updated serial numbers and site locations?	MOH agency, partner sites, SCMS, CDC etc.	Ideally there should be a complete list of all instruments in the country, their location, serial numbers and age of each machine at minimum. This will help inform decision making on the diagnostic burden, contribution and utilization of the existing instruments. It will also help to manage maintenance contracts as well as vendor performance. In a mature program this data could possibly be obtained

		from the logistics system or Assets Management System (AMS), where available. This could be as simple as Excel Spreadsheet that can be used to track the information on regular basis or use of generic off the shelf asset management tool.